## REMARKS

In the Office Action, the Examiner noted that: Claims 1-61 are pending in the application, of which Claims 1-36 are withdrawn from consideration; Claims 37-53 and 55-61 are rejected; and Claim 54 is objected to.

By the present amendment, Claims 37, 51-53, 60, and 61 have been cancelled; and Claims 38, 39, 40, 41, 42, 43, 45, 54, 55, and 57-59 have been amended.

Thus, as of the present amendment, Claims 1-36, 38-50, and 54-59 are pending of which Claims 1-36 are withdrawn from consideration; and Claims 38-50, and 54-59 are under consideration.

### Response to Office Action Paragraphs 2-4
### Claim Rejection Under 35 U.S.C. §112

In the Office Action the Examiner rejected Claim 55 under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner stated that "Claim 55 recites the limitation "immunosuppressive substance" in line 6" and that "There is insufficient antecedent basis for this limitation in the claim.

By the present amendment Claim 55 has been cancelled without prejudice.

### Response to Office Action Paragraphs 5-6
### Claim Rejection Under Double Patenting

In the Office Action the Examiner provisionally rejected Claims 52-59 and 61 under the judicially created doctrine of obviousness-type double, over the copending Application No. 09/783,254 (although the Office Action referred to USPA Serial No., 09/782,804, Applicants believe that USPA Serial No. 09/783,254 was the intended application).

Applicants respectfully acknowledge this rejection and will address this rejection once the claims are otherwise in condition for allowance.

**Response to Office Action Paragraphs 7-8**
**Claim Rejection Under 35 U.S.C. §102**

In the Office Action the Examiner rejected Claims 37, 42-53, 55 and 60 under 35 U.S.C. §102(b) as being anticipated by Harish et al. (USPN 6,506,437).

In rejecting the claims, the Examiner stated that "Harish et al. disclose a vascular stent (10) coated with therapeutic agents, such as methylprednisolone and mehotrexate as is with polymeric coatings with methylprednisolone as is claimed (Abstract, column 1 lines 15-38, column 2 lines 1-43, column 4 lines 10-20, column 6 lines 13-25 and 37-67 and column 7 lines 1-52)."

Harish et al. is directed to methods of coating an implantable device, such as a stent or a graft, having a plurality of depots formed in a surface thereof. An exemplary method includes applying a composition including a polymer and a solvent to the implantable device proximate to the depots. The compositions employed in the methods may include one or more therapeutic substances. Among a long list of agents that can be employed as the therapeutic substance in the composition, Harish et al. names methylprednisolone. Harish et al. goes on further to disclose generally, a range of weight percentage for the therapeutic substance as incorporated into the polymer. Harish et al. does not disclose any actual weights of the components of the composition.

By the present amendment, Claims 37, 51-53, 55, and 60 have been cancelled without prejudice.

Claims 42 & 44. Claim 42 has been rewritten in independent form, reciting in part: "releasing methylprednisolone and at least one other substance simultaneously with methylprednisolone from the prosthesis."

In contrast to the present invention, Harish et al. does not provide any teachings regarding the temporal release relationship between any of the substances let alone methylprednisolone and another substance.

Applicants submit that Claim 42, as amended, is not anticipated by or obvious in view of Harish et al., and it is patently distinguishable over the same.

Applicants respectfully request withdrawal of this rejection and the allowance of Claim 42, and all claims depending directly or indirectly therefrom.

Claims 43 & 44. Claim 43 has been rewritten in independent form, reciting in part: "releasing methylprednisolone and at least one other substance sequentially with methylprednisolone from the prosthesis."

As stated above in reference to Claim 42, in contrast to the present invention, Harish et al. does not provide any teachings regarding the temporal release relationship between any of the substances let alone methylprednisolone and another substance.

Applicants submit that Claim 43, as amended, is not anticipated by or obvious in view of Harish et al., and it is patently distinguishable over the same.

Applicants respectfully request withdrawal of this rejection and the allowance of Claim 43, and all claims depending directly or indirectly therefrom.

Claims 45 & 46-50. Claim 45 has been rewritten in independent form, reciting in part: "releasing Methylprednisolone wherein the releasing comprises delaying substantial release of methylprednisolone for at least one hour following implantation of the prosthesis."

As stated above with respect to Claim 42, in contrast to the present invention, Harish et al. does not provide any teachings regarding the temporal release conditions, including delayed release, of methylprednisolone or any other substance.

Applicants submit that Claim 45, as amended, is not anticipated by or obvious in view of Harish et al., and it is patently distinguishable over the same.

Applicants respectfully request withdrawal of this rejection and the allowance of Claim 45, and all claims depending directly or indirectly therefrom.

**Response to Office Action Paragraphs 9-10**
**Claim Rejection Under 35 U.S.C. §103**

In the Office Action the Examiner rejected Claims 38-41, 56 and 61 under 35 U.S.C. §103(a) as being unpatentable over Harish et al. (USPN 6,506,437).

In rejecting the claims, the Examiner stated that "Harish et al. is as explained before. Harish et al. fail to disclose the rate which the therapeutic agents are released from the stent as claimed in claims 38-41 and 56." The Examiner further stated that "It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the rate which the therapeutic agents are released from the stent as claimed in claims 38-41 and 56, since it has been held that where the general conditions of claims are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233."

By the present amendment, Claim 61 has been cancelled without prejudice.

Applicants respectfully disagree with the rejection and Examiner's reason.

As stated in In re Lindell, 155 USPQ 521, 523 (C.C.P.A. 1967), "Furthermore, application of the "obvious to try" test would often deny patent protection to inventions growing out of well planned research which is, of course, guided into those areas in which success is deemed most likely. These are, perhaps, the obvious areas to try. But resulting inventions are not necessarily obvious. Serendipity is not a prerequisite to patentability. Our view is that 'obvious to try' is not a sufficiently discriminatory test."

"At best, in view of these disclosures, one skilled in the art might find it obvious to try various combinations of these known scale and corrosion prevention agents. However, this is not the standard of 35 U.S.C. §103." In re Geiger, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987)

Claims 38 & 39. Claim 38, previously depending from Claim 60, has been rewritten in an independent form reciting, in part: "releasing methylprednisolone from the prosthesis at a rate between 5 μg/day to 200 μg/day."

Harish et al. makes no mention of any general conditions regarding the release rate of the therapeutic agents, let alone the specifics of release as presently claimed in amended Claim 38, and as such Applicants believe that Harrish et al. is an improperly cited as a reference against Claims 38 and 39.

Applicants respectfully submit that Harish et al. does not teach or suggest the present invention as presently stated in Claims 38 and 39 and that these claims and any depending directly or indirectly therefrom, are patentably distinguishable over Harish et al.

Applicants respectfully request withdrawal of this rejection and the allowance of Claims 38 and 39, and any depending directly or indirectly therefrom.

Claims 40 & 41. Claim 40, previously depending from Claim 60, has been rewritten in an independent form reciting, in part: "releasing methylprednisolone is released from the prosthesis within a time period of 1 day to 45 days in a vascular environment."

Harish et al. makes no mention of any sort of period of release, in general or in specific as presently claimed in amended Claim 40, and as indicated in reference to Claim 38, above, Harrish et al. is improperly cited as a reference against Claims 40 & 41.

Applicants respectfully submit that Harish et al. does not teach or suggest the present invention as presently stated in Claims 40 and 41 and that these claims and any depending directly or indirectly therefrom, are patentably distinguishable over Harish et al.

Applicants respectfully request withdrawal of this rejection and the allowance of Claims 40 and 41, and any depending directly or indirectly therefrom.

Claim 56. As indicated with reference to Claims 40 & 41, Harrish et al. does not provide any teachings with respect to the release period for methylprednisolone or any other substance.

Applicants respectfully request withdrawal of this rejection and the allowance of Claims 56, and any depending directly or indirectly therefrom.

## Response to Office Action Paragraph 11

## Allowable Subject Matter

Applicants note with appreciation the indication that Claims 54 will be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims.

By way of present amendment, Claim 54 has been rewritten in independent form in include all limitation of its respective base claim and are thus is in condition for allowance.

Applicants respectfully request the allowance of newly amended Claims 54.

For these reasons, Applicant believes that all claims are in condition for allowance and request that the Application be passed to issue at an early date.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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